

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

IN RE: TESTOSTERONE  
REPLACEMENT THERAPY PRODUCTS  
LIABILITY LITIGATION

Case No. 1:14-cv-01748

Hon. Judge Matthew F. Kennelly

This Document Relates to All Cases

**CORRECTED**  
**CASE MANAGEMENT ORDER No. 15 -**  
**Protocol for electronically stored information (ESI) production format**

It is hereby **ORDERED** as follows:

**A. SCOPE**

1. **General.** The procedures and protocols set forth in this Agreement shall govern the production of ESI in this matter, unless the Parties agree in writing to change them or they are changed by the Court at the request of a Party. The Parties agree to adhere to Federal Rule of Civil Procedure Rule 1 such that the claims and defenses can be resolved in the most just, speedy and inexpensive manner, and that discovery measures that do not reasonably or meaningfully lead to resolutions of the claims and defenses in this matter should be avoided to reduce cost and time. To the extent that third parties may produce documents in this case, the Parties agree to request that such third parties to adopt this Agreement.
2. **Disputes.** The Parties shall meet and confer in good faith on any issue regarding ESI, as necessary, including any relating to custodians and data sources, that arise under this Agreement or otherwise. In the event the Parties cannot reach an agreement on a disputed matter, the Parties shall submit the matter to the Court. A Party wishing to file a motion with the Court must give at least ten (10) days' advance notice in writing, stating the subject matter of the dispute. The Parties shall meet and confer with respect to the disputed issue within the 10-day period. If the Parties are unable to reach agreement, a Party may then file a motion.
3. **Proportionality.** The proportionality standards set forth in Federal Rule of Civil Procedure 26(b)(2)(C), Rule 26(g), and Principle 1.03 (Discovery Proportionality) of the 7<sup>th</sup> Circuit Electronic Discovery Principles shall be applied in all matters related to discovery of ESI, including without limitation the preservation, collection, and production of such information. To further the

application of the proportionality standard, requests for production of ESI and related responses shall be reasonably targeted, clear, and as specific as practicable.

4. **Cooperation.** The cooperation standards set forth in Principle 1.02 (Cooperation) and Principle 2.01 (c) and (d) (Duty to Meet and Confer) of the 7<sup>th</sup> Circuit Electronic Discovery Principles shall be applied in all matters related to discovery of ESI. The attorneys for each party shall review and understand how their client's data is stored and retrieved before the meet and confer discussions in order to determine what issues must be addressed during the meet and confer discussions. If the Court determines that any counsel or party in a case has failed to cooperate and participate in good faith in the meet and confer process or is impeding the purpose of the Principles, the Court may require additional discussions prior to the commencement of discovery, and may impose sanctions, if appropriate.

Nothing in this Protocol alters a Party's rights, obligations, and responsibilities under the applicable Federal Rules of Civil Procedure and applicable decision authority, nor does anything in this Protocol impose additional burdens beyond those imposed by the Federal Rules of Civil Procedure and applicable decision authority. The Parties reserve all objections under the Federal Rules of Civil Procedure and applicable decision authority for matters relating to the production of data that are not specifically addressed in this Protocol.

## **B. DEFINITIONS**

1. **"Metadata"** means: (i) information embedded in a Native File that is not ordinarily viewable or printable from the application that generated, edited, or modified such Native File; and (ii) information generated automatically by the operation of a computer or other information technology system when a Native File is created, modified, transmitted, deleted or otherwise manipulated by a user of such system.
2. **"Native Format"** means and refers to the format of ESI in which it was generated or as it is ordinarily maintained by the Producing Party in the usual course of its business and in its regularly conducted activities.
3. **"Static Image(s)"** means a representation of ESI produced by converting a Native File into a standard image format capable of being viewed and printed on standard computer systems. A Tagged Image File Format (TIFF) image is an example of a Static Image.
4. **"OCR"** means the optical character recognition file which is created by software used in conjunction with a scanner that is capable of reading text-based documents and making such documents searchable using appropriate software.
5. **"Extracted Text"** means the text extracted from a Native File and includes all header, footer and document body information.

6. **"Party"** or **"Parties"** means or refers to the named Plaintiffs and/or Defendants in the cases transferred into In Re Testosterone Replacement Therapy Products Liability Litigation, Case No. 14-CV-01748, as of April 4, 2014.

**C. PROPORTIONALITY AND SEARCH TERM PROTOCOL**

**1. Custodians and Data Sources.**

Within twenty-one (21) days from the case management conference, Defendants shall provide to Plaintiffs an initial list of key custodians. If Plaintiffs request that additional key custodians and databases or systems be identified from any Defendant, the Defendant shall meet and confer in good faith with Plaintiffs within seven (7) days of the request. If the Parties cannot come to an agreement, the Parties shall seek resolution of the issue by the Court.

2. **Use of Search Terms.** To ensure proportionality and exclude ESI that is not relevant to the matter, the Parties agree to meet and confer to discuss the use of reasonable search terms and date ranges as a means to identify relevant ESI for review and production, with an expectation that the Parties will reach an agreement on a set of search terms against an agreed-upon list of sources. Nothing in this paragraph shall operate to limit a party's obligations under the Federal Rules of Civil Procedure and applicable decisional authority.

- a. It is understood that the search may likely be an iterative process. Once a search protocol has been agreed to and executed, it may likely need to be refined. However, the Parties will make best efforts to ensure that the first search term list is thorough and appropriate as a first list can be. Upon a reasonable request to further expand or limit the use of search terms, the Parties will meet and confer and attempt in good faith to reach agreement. If the Parties cannot reach agreement, any dispute shall be presented to the Court.
- b. In the event that any party determines in good faith, after attempting to use the agreed search terms, that its use of any of those search terms is unreasonably burdensome and inefficient, then it shall meet and confer with the party that propounded the document request to which it is responding. The propounding party shall negotiate in good faith to modify the agreed search terms. In the absence of a mutually acceptable agreement to modify the agreed searched terms, the responding party may apply to the Court to modify the terms of this protocol.
- c. The fact that one or more search terms is found in a file, document, or other specific ESI does not establish relevance, responsiveness, or discoverability.

**3. Prioritized Searching.**

- a. **Data Sources that are Reasonably Accessible.** The Parties agree that any search for relevant and discoverable documents shall initially involve searching for such documents in the data sources within which such documents are reasonably accessible.
  - b. **Data Sources that are Not Reasonably Accessible.** The Producing Party shall identify, and provide to the requesting Party, reasonable descriptions of those categories of data sources that it claims are not reasonably accessible because of undue burden or cost. If the requesting Party disputes the identification of such categories as not reasonably accessible, the Parties shall meet and confer in good faith to resolve the matter before raising any issues before the Court. On-site inspections of electronic media under Federal Rule of Civil Procedure 34(b) shall not be permitted, absent agreement of the Parties or where good cause and specific need have been demonstrated.
4. **De-duplication of Production.** The Parties shall use reasonable, good faith efforts to avoid the production of duplicate ESI, and shall meet and confer regarding the potential use of email threading, de-duplication vertically within each custodian or horizontally across custodians, the means by which duplicates will be identified, and the potential production of a de-duplication log or metadata for de-duplicated documents.

**D. PRIVILEGE**

The handling of privilege, including advertent disclosures, clawback procedure, claims of privilege, limits to privilege log content, and challenges to privilege are addressed in the Protective Order.

**E. PRODUCTION**

1. **ESI Production Format.** The following provisions shall generally govern the production format and procedure for ESI and are subject to the other provisions contained herein.
  - a. **Prior Productions.** If a Party is ordered to produce physically-stored or electronically-stored information previously produced in another case, proceeding, or government investigation, the Parties will further meet and confer as the need arises.
  - b. **Production of ESI.** The Parties have met and conferred and will continue to meet and confer regarding production format.
    - i. **Production of Certain Files in Native Format.** The Parties have agreed that Excel spreadsheets and audio and video files shall be produced in their native format unless redacted. Native files will be accompanied by load and metadata files containing the fields identified in the attached Exhibit A, including confidentiality

designations. The Parties will meet and confer further regarding any additional metadata fields.

ii. **Production of Other ESI in TIFF.** Defendants shall produce other ESI (e.g., emails, word processing files, and presentation files) in .tif format. ESI shall be produced in black-and-white, single page, 300 DPI, Group IV\*.tif images with affiliated metadata as identified below. The Parties will accommodate reasonable requests for production of specific images in color. The Parties will meet and confer in good faith to determine the nature and extent of objective coding which may be captured or created by Producing Party's collection or review processes or platforms, and whether any such information will be produced to Plaintiffs.

iii. Any productions made in TIFF will include these additional specifications:

- a load file for images;
- a delimited load file (.dat) containing a field with the full path and filename to native files produced and the metadata fields identified in the attached Exhibit A (for ESI);
- document level .txt files for all native documents containing extracted full text or OCR text (OCR only if extracted text is not available or if the document has been redacted);
- Bates number branding and appropriate Confidentiality designations (if any) on the face of the image.

c. **Image Load File Requirements.** In general, image load files will meet these requirements. The Parties agree to meet and confer further if meeting these requirements is not reasonably possible.

- Every Document referenced in a production image load file shall have all corresponding images, text, and data logically grouped together in a directory structure with a common key to properly load the data.
- Documents shall be produced in only one image load file throughout the productions, unless that document is noted as being a replacement document in the Replacement field of the data load file.

- The name of the image load file shall mirror the name of the delivery volume, and should have an .lfp, .opt or .dii\* extension (e.g., ABC001.lfp). The volume names shall be consecutive (i.e., ABC001, ABC002, et. seq.) \*If .dii file is produced, the accompanying metadata load file shall be separate from the .dii file and not contained within the .dii file.
- The load file shall contain one row per Tiff image.
- Every image in the delivery volume shall be contained in the image load file.

The image key shall be named the same as the Bates number of the page. Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.), i.e., a separate volume shall be created for each piece of media delivered.

- d. **Metadata Load File Requirements.** In general, metadata load files will meet these requirements. The Parties agree to meet and confer further if meeting these requirements is not reasonably possible.

- The metadata load file shall use the following delimiters:
  - Column Delimiter: Pipe – | (ASCII 124)
  - Text Qualifier: Caret – ^ (ASCII 94)
  - New line: Registered sign - ® (ASCII 174)
- Data for each document shall be produced in only one data load file throughout the productions, unless that document is noted as being a replacement document in the Replacement field of the data load file.
- The first record shall contain the field names in the order of the data set forth in Exhibit A. Metadata fields that are not applicable to a document shall be filled with a NULL value along with fields that were not able to be obtained due to a processing error or corrupt file.
- All date fields shall be produced in "mm/dd/yyyy hh:mm:ss AM" format, to the extent available.
- A carriage-return line-feed shall be used to indicate the start of the next record.
- Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.); a separate volume shall be created for each piece of media delivered.

- The name of the metadata load file shall mirror the name of the delivery volume, and shall have a .dat, .csv or .txt extension (i.e., ABC001.dat).
  - The volume names shall be consecutive for each produced source. (i.e., ABC001, ABC002, et. seq.).
- e. **Embedded Objects.** Objects embedded in Microsoft Word, .rtf, Powerpoint or Excel will be extracted as separate documents and produced as attachments to the document.
- f. **Compressed Files.** Compression file types (i.e., .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual folders and/or files.
- g. **Dynamic Fields.** The Parties will meet and confer about the possibility of forcing off dynamic fields such as AutoDate.
- h. **Appearance and Content.** No document may be intentionally manipulated to change how the source document would have appeared if printed out to a printer attached to a computer viewing the file, without prior agreement of the Receiving Party. Therefore, subject to any appropriate redaction, each document's electronic image shall convey the same information and image as the original document.
- i. **Document Numbering for TIFF Images.** Each page of a document produced as TIFF images shall have a legible, unique Bates Number electronically "burned" onto the image at a location that does not obliterate, conceal or interfere with any information from the source document. The Bates Number for each document shall be created so as to identify the Producing Party and the Bates Number. Each Party shall have a unique identifying name. Each page of each production shall have a unique number of up to eight digits. The unused digits of the unique number shall be filled with placeholder zeros (0) to facilitate electronic sorting of the documents. The Bates number will (i) be consistent across the production; (ii) contain no special characters; and (iii) be numerically sequential within a given document. Attachments to documents will be assigned Bates numbers that directly follow the Bates numbers on the documents to which they were attached. If a number or set of numbers is skipped in a production, and not otherwise identified on a privilege log, the producing party will disclose those numbers or ranges in a cover letter accompanying the production.
- j. **Replacement Files.** Any documents that are replaced in later productions shall be clearly designated as such, by appending a "-R" to the production prefix and by a letter accompanying the production clearly designating such documents as replacements.

- k. **Production Media.** The Producing Party shall produce documents on readily accessible, computer or electronic media as the Parties may hereafter agree upon, including CD-ROM, DVD, external hard drive (with standard PC compatible interface or access to a secure On-Line Repository agreed upon by the Parties) or via secure FTP site. Each piece of Production Media shall be assigned a production number or other unique identifying label corresponding to the date of the production of documents on the Production Media as well as the sequence of the material in that production. The Producing Party shall accompany all document productions with a transmittal cover letter identifying by Bates number the documents produced.
- l. **Redactions.** To the extent that a document is produced in redacted form or with redacted metadata, the Parties will meet and confer on whether a metadata field will provide sufficient information such that a redaction log and suppressed metadata log may not be necessary. Redactions in general are addressed in the Protective Order.
- m. **Database Records.** To the extent that any Party requests information that is stored in a database or database management system, the Parties will meet and confer regarding the accessibility of such information and the format of production.
- n. **Non-Standard Files.** Parties will meet and confer with regard to the treatment of non-standard electronic files, include, but are not limited to, source code, transactional data, database files, and proprietary applications not publicly available.
- o. **Exceptions.** With each production, the Producing Party shall identify any potentially relevant ESI which could not be produced and/or imaged because of technical issues: for example, corruption, unavailable password protection, proprietary software, etc. The Parties will meet and confer on a reasonable and cost-effective means of further investigating and resolving the technical issues.
- p. **Time Zone.** Unless otherwise agreed, all dynamic date and time fields, where such fields are processed to contain a value, and all metadata pertaining to dates and times will be standardized to Eastern Time. The Parties understand and acknowledge that such standardization affects only dynamic fields and metadata values and does not affect, among other things, dates and times that are hardcoded text within a file. Dates and times that are hard-coded text within a file (for example, in an email thread, dates and times of earlier messages that were converted to body text when subsequently replied to or forwarded; and in any file type, dates and times that are typed as such by users) will be produced as part of the document text in accordance with the load file formats, below.



2. **Confidentiality of Produced ESI.** Responsive ESI, whether produced as TIFF images or in Native Format, shall be produced pursuant to the terms of the Stipulated Discovery Confidentiality Order. Any objections to production shall be made pursuant to the Federal Rules of Civil Procedure or the Federal Rules of Evidence. If a document is produced subject to a claim that it is protected from disclosure under the Stipulated Discovery Confidentiality Order, the word "CONFIDENTIAL" or "ATTORNEY'S EYES ONLY" shall be burned electronically on each page of such document.
3. **Encryption.** To maximize the security of information in transit, any media on which documents are produced may be encrypted by the Producing Party. In such cases, the Producing Party shall transmit the encryption key or password to the requesting Party, under separate cover, contemporaneously with sending the encrypted media.

**F. MISCELLANEOUS**

1. **English Language.** To the extent any Data exists in more than one language, the Data shall be produced in English, if available. If no English version of a document is available, the Producing Party does not have an obligation to produce an English translation of a document.
2. **Variance.** Any practice or procedure set forth herein may be varied by written agreement of the Parties.

**G. OBJECTIONS TO ESI PRODUCTION**

If either Party objects to producing the requested ESI on the grounds that such information is not reasonably accessible because of undue burden or cost, or because production in the requested format would impose undue burden or cost, the Party shall describe the nature of the objection with reasonable particularity. This notification should occur promptly and before the production is due under the Federal Rules of Civil Procedure. If possible, the notifying party should describe potential alternative sources or production formats. The Parties will meet and confer in an attempt to resolve the objections if necessary.

**H. PAPER DISCOVERY**

The Parties have agreed to further meet and confer about the technical specifications related to the production of hard copy documents.

IT IS SO ORDERED.

  
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HONORABLE MATTHEW F. KENNELLY  
UNITED STATES DISTRICT JUDGE

Dated: November 4, 2014

**Exhibit A - Fields and Metadata To Be Produced**

<b>Field</b> (to the extent available and/or unredacted)	<b>Data Type</b> (to the extent available and/or unredacted)	<b>Field Description for Electronic Documents</b>	<b>Field Description for Emails</b>
BegDoc	Fixed Length Text	Start Bates	Start Bates
EndDoc	Fixed Length Text	End Bates	End Bates
BegAttach	Fixed Length Text	Starting Bates number of document family	Starting Bates number of document family
EndAttach	Fixed Length Text	Ending Bates number of document family	Ending Bates number of document family
Author	Long Text	Document author from metadata	
LastSavedBy	Long Text	Contents of this metadata field from application metadata, or an equivalent (if any)	
From	Long Text		Contents of this metadata field, or an equivalent
To	Long Text		Contents of this metadata field, or an equivalent
CC	Long Text		Contents of this metadata field, or an equivalent
BCC	Long Text		Contents of this metadata field, or an equivalent
Subject	Long Text		Contents of this metadata field, or an equivalent
Title	Long Text	Title from a document's properties	
SentDate	Fixed Length Text (mm/dd/yyyy)		Sent date of the email
SentTime	Fixed Length Text (hh:mm AM/PM)		Sent time of the email
ReceivedDate	Fixed Length Text (mm/dd/yyyy)		Received date of the email
ReceivedTime	Fixed Length Text (hh:mm AM/PM)		Received time of the email
TimeZone	Fixed Length Text (PST, MST, CST, EST, GMT)	Time zone used for processing	Time zone used for processing
ModDate	Fixed Length Text (mm/dd/yyyy)	Contents of this metadata field, or an equivalent	
ModTime	Fixed Length Text (hh:mm AM/PM)	Contents of this metadata field, or an equivalent	
CreateDate	Fixed Length Text (mm/dd/yyyy)	Contents of this metadata field, or an equivalent	
CreateTime	Fixed Length Text (hh:mm AM/PM)	Contents of this metadata field, or an equivalent	
NativeLink	Fixed Long Text	Link to the native file (if any)	Link to the native file (if any)
FileName	Long Text	Contents of "File name" metadata field	Contents of "File name" metadata field
FilePath	Long Text	File path of the document, excluding file name	
Custodian	Long Text	Custodian designation where appropriate	Custodian designation where appropriate

<b>Field</b> (to the extent available and/or unredacted)	<b>Data Type</b> (to the extent available and/or unredacted)	<b>Field Description for Electronic Documents</b>	<b>Field Description for Emails</b>
AttachCount	Whole Number		Number of attachments of a given parent document (only populated for parent documents)
FileSize	Whole Number	Size of the file in bytes	Size of the file in bytes
FileExt	Fixed Length Text	File extension	File extension
MD5Hash	Fixed Length Text	MD5 hash of the document	MD5 hash of the email
Conversation_Index	Long Text		Value assigned to a conversation by the Exchange server
RevisionNo	Fixed Length Text	“Revision number” from application metadata (if any)	
PgCount	Whole Number	Number of pages (TIFF documents only)	Number of pages (TIFF documents only)
Extracted Text	Long Text	Path to the body text file for the document	Path to the body text file for the email
Dupe_Custodians <sup>1</sup>	Long Text	All/other custodians of a de-duplicated document (if applicable)	All/other custodians of a de-duplicated email (if applicable)
Exceptions <sup>2</sup>	Fixed Length Text	Produced document that cannot be processed (field to be populated with “Yes”)	Produced email or attachment that cannot be processed (field to be populated with “Yes”)
Confidentiality	Fixed Length Text	Document’s designated confidentiality	Document’s designated confidentiality

<sup>1</sup> Parties will continue to meet and confer further regarding this metadata field per the ESI order. *See* Order Establishing Protocol for Electronically Stored Information (“ESI”) Production Format, Section C.4.

<sup>2</sup> To the extent any Defendant is not able to create a metadata field for exceptions as defined here, the parties will further meet and confer.